

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0942826	<b>(X3) Date Survey Completed</b> 04/01/2019
<b>Name of Provider or Supplier</b> Intermountain River Road Draw Station	<b>Street Address, City, State</b> 577 S River Rd, St George, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5461</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(6)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review and confirmation by staff, the laboratory failed to perform controls prior to testing patients for 1 of 3 prothrombin time test cartridge lot number quality control reviewed. The laboratory performed approximately 100 Protime tests per year. Findings include: 1. Patient test records review for patient 519588992 tested on 07/02/1018 included the lot number of T18122 for the iSTAT prothrombin time cartridge used to test the patient's sample. 2. Quality control record review included documentation Cartridge lot number T18122 was quality controlled on 07/04/2018, two days after the patient was tested. 3. In an interview with staff on 04/01/2019 at approximately 11:00 A.M., the technical consultant and laboratory manager confirmed quality control was not performed prior to testing patient samples.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on Individualized Quality Control Plan (IQCP) procedure review, lack of documentation, and confirmation by the technical consultant, the director failed to document the laboratory followed their procedure to review the IQCP annually to verify the reduced frequency of quality control performance was sufficient and the reduced frequency did not adversely effect testing quality for Prothrombin time tests utilizing an IQCP to perform quality control at a reduced frequency, 120 prothrombin time tests per year. Findings include: 1. The IQCP reviewed lacked documentation the director reviewed the IQCP against the quality assessment documentation to evaluate the plan's adequacy since approved in November 2016. 2, In an interview with staff on 04/01/2019 at approximately 2:30 P.M., staff confirmed the IQCP had not been reviewed since it was implemented in November 2016.